

### REMARKS

This amendment is responsive to the non-final office action mailed November 1, 2005. Existing claims 1-37 have been cancelled and replaced by new claims 38-65. These new claims read on Species II (Figures 5&6) previously elected by the Applicant on March 22, 2004 in response to a restriction requirement. No new matter has been introduced. The new claims are submitted solely to clarify the claimed invention and expedite prosecution, and not for reasons related to patentability. The currently pending claims in this application are 38-65. Favorable consideration and allowance of all pending claims is respectfully requested.

Claims 1, 3-9, and 26-37 were rejected under 35 U.S.C. 102(b) as being anticipated by Larsen in EP 0834281. This rejection is rendered moot by the cancellation of these claims. New claims 38-65 are clearly distinguishable from Larsen as explained herein.

New independent claims 38, 50, and 58 are directed to a device for attaching a fixation element to bone. These claims all similarly require a fixation element holding sleeve that is movable to a position at least partially retracted into the handle.

Claim 38 further requires "a driver shaft having a distal end defining a solid tip portion configured to abuttingly contact the fixation element, the shaft axially slideable inside the sleeve from a first position in which the tip portion is withdrawn from the distal end of the sleeve to a second position in which the tip portion projects beyond the distal end of the sleeve ... wherein the shaft is movable to the second position with a fixation element held in the sleeve to eject the fixation element from the sleeve."

Claim 50 similarly further requires "a driver shaft attached to the handle and axially slideable inside the sleeve, the shaft having a distal end defining a solid tip portion configured to abuttingly contact the fixation element, the tip portion at least partially recessed inside the sleeve when the sleeve is in the second position ... wherein with a fixation element held in the sleeve, the tip portion of the shaft projects beyond the sleeve when the sleeve is moved from the first position to the second position to eject the fixation element from the sleeve."

Claim 58 similarly further requires “a driver shaft attached to the handle and axially slideable inside the sleeve from a proximal position to a distal position, the shaft having a distal end defining a solid tip portion configured to abuttingly contact the fixation element ... wherein with a fixation element held in the sleeve, the tip portion of the shaft projects beyond the sleeve when the shaft is moved to the distal position to contact and eject the fixation element from the sleeve.”

Larsen does not teach or fairly suggest a fixation element attachment device having at least the foregoing features required by claims 38, 50, and 58. Furthermore, claim 58 further requires “the proximal end of the sleeve having a resilient portion bendable in a radial direction to releaseably engage the handle.” This limitation is also not taught or fairly suggested by Larsen. Accordingly, Applicant’s new independent claims are clearly distinguishable from Larsen and believed to be allowable.

Larsen is directed to a suture anchor installation device. Larsen does not disclose a driver shaft having a distal end defining a “solid tip portion configured to abuttingly contact the fixation element” for releasing the element from the sleeve, as recited in Applicants’ claims 38, 50, and 58. In contrast, plunger rod 260 in Larsen, which is slidably disposed in outer sheath tube 250, has an opening 267 in distal end 261 “to releaseably engage the proximal end portion of legs 15 of the suture anchor.” (Larsen, Col. 6, lines 15-20.) Indeed, as clearly shown in Figures 6-8, Larsen discloses that plunger rod 260 receives and holds the suture anchor independently of the sheath tube 250 even before the rod is retracted into the distal end of the sheath tube (*see* Figure 8). Accordingly, Larsen’s distal end of rod 260 clearly does not have a solid tip portion configured to abuttingly contact the fixation element, which releases the element from the sleeve, as required by Applicant’s claims and is clearly distinguishable.

Furthermore, Larsen does not disclose a fixation element attachment device having a driver shaft which in one position projects a solid tip portion beyond the sleeve to eject a fixation element from the sleeve, as required by Applicant’s claims 38, 50, and 58. This movement causes the solid tip portion of the shaft to abuttingly contact the fixation element and disengage it from the outer holding sleeve which releaseably holds the fixation element. In Applicant’s claimed device, this is achieved by an outer sleeve that holds the fixation element while an inner shaft functions as a driver. By contrast, Larsen shows in Figures 6-7 that projecting inner

plunger rod 260 beyond sheath tube 250 does not eject the fixation element (suture anchor 10) from the plunger rod (*see, e.g.*, Larsen Figures 6-8 ) because the inner plunger rod actually holds the fixation element.<sup>1</sup> In Larsen, retracting outer sheath 260 serves a distinctly different purpose when driving the suture anchor into bone which is to release suture 30 from pinch plate 217 in handle 210. The insertion tool may then be extracted allowing a surgeon to tie the sutures to reattach ligaments or muscles to the bone (*see* Larsen, Col. 9, line 52-Col. 10, line 17.) Furthermore, Applicant's claimed inner shaft advantageously provides a surgical fixation element insertion device that positively drives out and disengages the fixation element from the installation device. By contrast, devices like Larsen rely on only the friction fit between the fixation element and bone to separate the element from the insertion tool, which may require the surgeon to rock the tool back and forth to disengage the fixation element possibly causing soft tissue damage. Accordingly, Applicant's invention claimed in claims 38, 50, and 58 is clearly distinguishable from Larsen for these additional reasons.

In addition to the foregoing reasons, claim 58 is further distinguishable from Larsen which does not teach or fairly suggest "the proximal end of the sleeve having a resilient portion bendable in a radial direction to releaseably engage the handle." This advantageously allows the sleeve to be removed for sterilization or replacement without disassembling the fixation element attachment device.

In sum, Larsen does not teach or fairly suggest each and every element of independent claims 38, 50, and 58. Accordingly, these claims are not anticipated by Larsen and believed to be allowable for the foregoing reasons.

Dependent claims 39-49, 51-57, and 59-65 depend directly or indirectly from independent claims 38, 50, and 58 and include all of their limitations. These dependent claims are also believed to be allowable based on the allowability of the independent claims from which

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<sup>1</sup> Although as the Examiner notes on page 3, paragraph 2 of the Office Action, Larsen claims that "the distal end of the sheath tube acts as a primary support for the suture anchor 10," this contradicts the clear disclosure of Larsen FIGS. 6-8 and Column 6, lines 15-20 as discussed herein. Note that in FIG. 8 outer sheath 250 does not even touch the anchor 10. Therefore, consistent with reading the entire disclosure of Larsen, "support" cannot reasonably be interpreted as meaning the outer sheath holds or retains suture anchor 10, and Larsen does not provide an enabling disclosure to one skilled in the art for a surgical anchor insertion tool wherein the outer sheath holds the anchor.

they depend and for the additional limitations added by the dependent claims which further distinguish over Larsen.

No new matter has been added. Support for the limitations of new claims 38-65 discussed herein can be found at least in Applicant's Figures 5 & 6 and page 5, line 6 to page 6, line 16 of the specification.

**CONCLUSION**

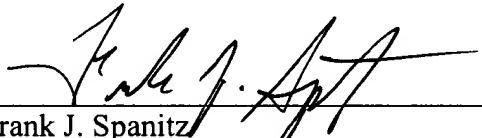
In view of the foregoing, Applicants respectfully request favorable consideration and allowance of all pending claims. Should the Examiner disagree with the allowability of any of the claims, the Examiner is respectfully requested to contact Applicants' undersigned representative at 212-309-6375 to help resolve any remaining issues and expedite this case.

Respectfully submitted,

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